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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/767,138 | 01/23/2001 | Marc Alizon | 2356.0010-04 | 2082 |

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EXAMINER

PARKIN, JEFFREY S

ART UNIT PAPER NUMBER

1648

DATE MAILED: 05/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 09/767,138 | Applicant(s) ALIZON ET AL. | |
| | Examiner Jeffrey S. Parkin, Ph.D. | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 65-72 is/are pending in the application.
- 4a) Of the above claim(s) 68-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-67 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

RD

Serial No.: 09/767,138
Applicants: Alizon, M., et al.

Docket No.: 2356.0010-04
Filing Date: 01/23/01

Detailed Office Action

Status of the Claims

Claims 1-64 were canceled without prejudice or disclaimer, claims 65-67 were previously amended, and new claims 68-72 submitted. Newly submitted claims 68-72 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are drawn to sundry envelope proteins with little or no structural similarity. Separate searches will be required for each protein. Accordingly, each of the claims is directed toward and independent and distinct invention. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 68-72 are withdrawn from further consideration as being directed towards a nonelected invention (refer to 37 C.F.R. § 1.142(b) and M.P.E.P. § 821.03).

35 U.S.C. § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 65-67 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. In *re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). In *re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims have been amended to recite purified HIV-1 viruses that encode variant HIV-1_{ELI} envelope glycoproteins that have specific amino acid residues (e.g., S⁶³, E⁶⁵, I⁷¹, I⁸⁷, E⁹⁰, D²⁴⁵, K²⁴⁷, and E⁵²⁶ (claim 65); S⁶³, E⁶⁵, I⁷¹, I⁸⁷, A/E⁸⁸, E⁹⁰, D²⁴⁵, K²⁴⁷, I/M²⁸⁶, Q/R⁵⁰⁹, E⁵²⁶, and K/Q⁶⁹⁷ (claim 66); S⁶³, E⁶⁵, A⁶⁸, I⁷¹, I⁸⁷, A/E⁸⁸, E⁹⁰, A²¹⁵, R²⁴⁴, D²⁴⁵, K²⁴⁷, I/M²⁸⁶, Q/R⁵⁰⁹, R⁵¹⁹, E⁵²⁶, and K/Q⁶⁹⁷ (claim 67)). The HIV-1 envelope is approximately 877 amino acids in length. The disclosure describes the isolation and molecular cloning of a novel HIV-1 isolate designated ELI. The nucleotide and amino acid sequences of this isolate were compared to other prototypical HIV-1 isolates (e.g., BRU, ARV-2, MAL). However, the disclosure clearly fails to provide adequate support for the currently claimed species. The specification clearly identifies the parent ELI sequence. However, the disclosure does not discuss desired or critical amino acid residues located within the ELI Env. The disclosure does not describe preferred variants of this sequence. Accordingly, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

Response to Arguments

Applicants traverse and submit that the specification provides "variants" of HIV-1_{ELI} having a nucleotide sequence different from that of the parent isolated (e.g., HIV-1_{MAL}). This argument is clearly not persuasive. The disclosure provides a limited number of different HIV-1 isolates. However, nothing in the disclosure would lead the skilled artisan to contemplate that applicants were in possession of an HIV-1 Env variant having the minimal structural requirements set forth (e.g., mutations at S⁶³, E⁶⁵, I⁷¹, I⁸⁷, E⁹⁰,

D²⁴⁵, K²⁴⁷, and E⁵²⁶). Thus, applicants' arguments are clearly not persuasive.

Written Description

Claims 65-67 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In *re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323 (C.C.P.A. 1981). In *re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90 (C.C.P.A. 1976). The claims have been amended to recite purified HIV-1 viruses that encode variant HIV-1_{ELI} envelope glycoproteins that have specific amino acid residues (e.g., S⁶³, E⁶⁵, I⁷¹, I⁸⁷, E⁹⁰, D²⁴⁵, K²⁴⁷, and E⁵²⁶ (claim 65); S⁶³, E⁶⁵, I⁷¹, I⁸⁷, A/E⁸⁸, E⁹⁰, D²⁴⁵, K²⁴⁷, I/M²⁸⁶, Q/R⁵⁰⁹, E⁵²⁶, and K/Q⁶⁹⁷ (claim 66); S⁶³, E⁶⁵, A⁶⁸, I⁷¹, I⁸⁷, A/E⁸⁸, E⁹⁰, A²¹⁵, R²⁴⁴, D²⁴⁵, K²⁴⁷, I/M²⁸⁶, Q/R⁵⁰⁹, R⁵¹⁹, E⁵²⁶, and K/Q⁶⁹⁷ (claim 67)). The HIV-1 envelope is approximately 877 amino acids in length. The disclosure describes the isolation and molecular cloning of a novel HIV-1 isolate designated ELI. The nucleotide and amino acid sequences of this isolate were compared to other prototypical HIV-1 isolates (e.g., BRU, ARV-2, MAL). Thus, the skilled artisan would reasonably conclude that applicants were in possession of this particular isolate. The disclosure does not describe the isolation and characterization of any other HIV-1 viruses with the claimed variant ELI envelope regions, particularly those with the recited genetic variation. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the other ELI variants at the time of filing.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the

inventor had possession of the claimed invention. See, e.g., *Vas-Cath, Inc., v. Mahurkar*, 935 F.2d at 1563, 19 U.S.P.Q.2d at 1116. The issue raised in this application is whether the original application provides adequate support for the broadly claimed genus of HIV-1 viruses carrying HIV-1_{ELI} envelope variants with the minimum requirements cited. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the biomolecule of interest. *In re Bell*, 991 F.2d 781, 26 U.S.P.Q.2d 1529 (Fed. Cir. 1993). *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q.2d 1210 (Fed. Cir. 1995). A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 U.S.P.Q.2d 1895, 1905 (Fed. Cir. 1995). The court noted in this decision that a laundry list² disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not reasonably lead those skilled in the art to any particular species.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. For some biomolecules, examples of identifying characteristics include a nucleotide or amino acid sequence, chemical structure, binding affinity, binding specificity, and molecular weight. The written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. Without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In the latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 U.S.P.Q.2d 1398, 1404, 1406 (Fed. Cir. 1997), cert. denied, 523 U.S. 1089 (1998). *In re Wilder*, 736 F.2d 1516, 1521, 222 U.S.P.Q. 369, 372-3 (Fed. Cir. 1984). Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention.

The claims are deficient as follows:

1) The disclosure only provides the nucleotide and amino acid sequence of a single HIV-1 ELI isolate. The disclosure does not describe any other variants of this sequence. Thus, applicants clearly did not contemplate making, isolating, and characterizing ELI envelope variants with the recited amino acid changes.

2) The disclosure fails to set forth specific ELI envelope variants. The claims recite a small number of preferred amino acids (e.g., 8, 12, or 16). However, the HIV-1 envelope is approximately 877 amino acids in length. Nothing in the disclosure would reasonably lead the skilled artisan to the currently claimed variants.

3) The disclosure fails to discuss preferred or critical molecular determinants that are required for any given variant. The claims recite preferred amino acid positions. However, there is nothing in the disclosure that leads the skilled artisan to the currently claimed combination of amino acids.

4) The disclosure fails to provide any structural/functional correlations between accepted amino acid substitutions. The claimed invention only specifies 8, 12, or 16 amino acids from a total of approximately 877. Thus, the claims allow for amino acid permutations ranging in value between 859 to 869. Absolutely nothing in the disclosure leads the skilled to any particular variant nor can the skilled artisan readily envisage, which of the multitude of possible amino acid substitutions, applicants contemplated making and using.

5) The state-of-the-art vis-à-vis the effects of single amino acid substitutions on envelope structure and function is one of unpredictability (Wang et al., 1995; Platt et al., 1997; Chen et al., 1998). Moreover, amino acid substitutions in other genes also clearly affect the replicative properties of the virus (Lee et al., 1997). Thus, the disclosure would need to provide considerable guidance in leading the skilled artisan to any particular ELI

variant. Accordingly, when all the aforementioned factors are considered in toto, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

Response to Arguments

Applicants argue that the disclosure provides a sufficient written description of the claimed invention. Specifically it was argued that the specification describes HIV-1_{ELI} variants and leads the skilled artisan to particular variants. These arguments are clearly not persuasive. Applicants have presented nothing more than a wish to obtain HIV-1 variants that were neither contemplated nor prepared. The courts have consistently ruled that a generic disclosure is insufficient to provide adequate written description for specific mutants. Nothing in the disclosure leads the skilled artisan to a viral envelope with the minimal structural characteristics recited (e.g., S⁶³, E⁶⁵, I⁷¹, I⁸⁷, E⁹⁰, D²⁴⁵, K²⁴⁷, and E⁵²⁶). Accordingly, the rejection is proper and maintained.

Finality of Office Action

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE

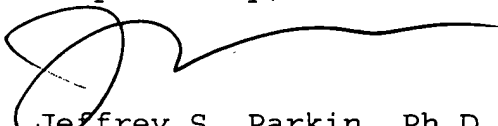
LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 10:30 AM to 9:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, James C. Housel, can be reached at (571) 272-0902. Direct general status inquiries to the Technology Center 1600 receptionist at (571) 272-1600. Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,



Jeffrey S. Parkin, Ph.D.
Primary Examiner
Art Unit 1648

11 May, 2005